

Exhibit B

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

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| IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION | Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE |
| THIS DOCUMENT RELATES TO: <i>Wave 3 Cases</i> | |

EXPERT REPORT OF MARC R. TOGLIA, M.D., FACOG

an isolated thread, Prolene polypropylene is used widely as a permanent and durable surgical suture. As a knitted material, polypropylene mesh is the consensus graft material in a number of areas in the human body. Specifically, type 1 mesh is universally recognized as possessing the highest biocompatibility with the least propensity for infection. (Ford Cochrane Review 2015). Differences in their efficacy and complications are likely to be due to several factors including the different knits and weaves of the various tape materials, their biomechanical properties and histological biocompatibility. Pore size affects the inflammatory response and resultant connective tissue formation within and into the mesh, and the rearrangement of materials such as collagen within the mesh structure. Macroporous meshes (pore size in excess of 75 μm) easily allow macrophages, leukocytes, fibroblasts, blood vessels and collagen to transverse the pores: thus macroporous meshes promote tissue host ingrowth with resultant biocompatibility and low risk of infection (Amid 1997).

Even prior to the development of the TVT device, the use of synthetic mesh slings for treatment of incontinence was well described (Morgan 1970; Nichols DH 1973; Stanton 1985). The earliest prototypes for the TVT device critically evaluated the use of a variety of these synthetic materials, such as Mersilene and Gortex before the Prolene mesh found higher exposure rates (Petros 2015; Ulmsten et al, 1996). These authors also reported that these materials (Gore-Tex, Teflon, Mersilene) were associated with significant inflammatory reaction in paraurethral tissues and caused a significant amount of tape rejection. (Falconer et al, 2001).

It is widely recognized that the creators of the TVT developed the procedure through thoughtful and extensive clinical documentation and scientific examination. The choice of a type 1, macroporous, monofilament polypropylene mesh became the obvious choice for the TVT device, based upon the experience referenced above. This material has been repeatedly demonstrated to offer the desired mechanical properties of durability and elasticity as well as excellent host tolerability and lack of evidence of rejection. Type 1 macroporous mesh with pore size > 75 microns allows for infiltration by macrophages, fibroblasts, blood vessels in angiogenesis and collagen fibers (Amid 1997).

The Prolene mesh utilizes a large pore size for a small 1.1cm wide strip of tape and promotes mechanical anchorage with collagen. The initial TVT trials with Prolene mesh showed no adverse reaction like impaired wound healing or tape rejection (Ulmsten et al, 1998). Biopsies of the paraurethral connective tissues two years after a TVT procedure confirmed no evidence of tissue reaction. (Falconer et al, 2001). While there was a significant foreign body reaction seen with Mersilene,

There has also been a claim that the particles from the mechanically cut mesh can lead to complications like pain and erosion. This is speculation and without reliable scientific support. In my searches and review of the clinical literature, and my attendance at specialty meetings and conferences, this is not a concern and particle loss has not been identified by any reliable scientific clinical studies as a cause of complications. The material in any particles would be the same Prolene polypropylene material used in the mesh. As discussed above the tolerability and biocompatibility of this material in women is established. Prolene sutures are also used in much larger quantities in other surgeries and surgeons for decades have hand cut mesh in the operating room. The long term clinical studies on TVT which show its efficacy, durability and safety have used mechanically cut mesh and the literature from before and after 2007 when laser cut mesh became available do not demonstrate a difference in clinical effect based on whether the mesh is cut mechanically or with a laser. Both behave the same under physiologic conditions. Of course either can have particle loss and rope under misuse such as removing the sheath and stretching the tape as plaintiffs' experts suggest, but that is not how TVT mesh is designed to be placed in women nor is it consistent with the TVT IFU and Professional education. High levels of force can be placed on the tape with the sheath on and the tape is not altered. Photographs referenced by plaintiffs' experts of the tape being stretched on a machine without the sheath or the trocars are not transferable to placement of the tape at the time of surgery. Overall, the theory that particles from mechanically cut TVT lead to adverse clinical effects in patients is not supported by the medical literature or my clinical experience having placed thousands of these slings. In my practice, I prefer the mechanically cut TVT mesh due to the way it handles in the operative suite and due to my long history of its use. I have also used laser cut mesh for SUI and have discerned no clinically significant difference or effect. This is more of an aesthetic theory not born out by reliable scientific data and it has not been differentiated as clinically significant by any of the pertinent surgical societies setting forth guidelines and analyses.

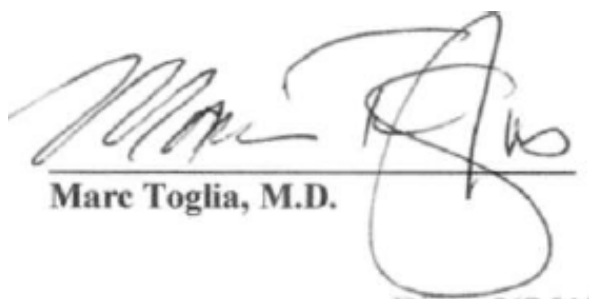
Some have raised concerns about the possibility of an adverse host tissue response to type 1 polypropylene mesh tape. These opinions are based largely upon studies involving animal models or studies involving abdominal hernia repairs. Studies that have specifically evaluated the pelvic floor tissue response are limited to small case series, and often are typically to a subset of subjects that have chronically extruded mesh implants. It is important to recognize that animal studies are not directly transferable to human subjects, and that individual tissue responses at different anatomic locations are likely to differ. They are also, in my opinion,

inconsistent with the extensive clinical experience with the TVT device referenced throughout this report which have shown that adverse events such as impaired wound healing, infection, or rejection are rare events. Furthermore, it is inappropriate to extrapolate data involving sheets of mesh to the much smaller surface area of the TVT device, as there are data showing that the surface of the implant, the fewer intolerance reactions are observed (Norris 1996, Cosson 2003). Similarly, mesh weight is directly related to the amount of mesh material implanted, again, making it inappropriate to extrapolate data on mesh sheets to the TVT device. Moreover, there is no recognized weight classification for midurethral slings, which are only 1.1cm in width. Differences in mesh architecture is also likely to affect tissue response, making the applicability of many of the studies cited by the plaintiff's experts to be highly questionable and of limited scientific value in regards to TVT. The weight of the small mesh tape in TVT is optimal for its intended use, to treat SUI on a long term basis and the long term studies and voluminous data show this.

A claim has been made by plaintiffs' experts suggesting a possible association between synthetic MUS based on rodent studies where sarcoma formation was reported after implantation of sheets of polypropylene. After an extensive review of the existing literature, I have concluded that these assertions lack scientific validity. These opinions are founded upon a report from 1958, when Oppenheimer et al identified the development of various sarcomas in rats implanted with sheets of plastic film (Cancer 1958; 11:204–213). Of note, the latency times to cancer formation ranged from 7 months to two years in this study. Interestingly, in some previous animal models, it was noted that surface area, shape and surface morphology had an impact on the risk of sarcoma development, with perforated materials having lower risks than solid, flat films of material (McGregor et al, Eur J Cancer 2000; 36:307–313). More recent animal studies evaluating monofilament and multifilament polypropylene mesh implantation in the subcutaneous tissues of mice did not corroborate these findings, with no sarcomas identified during two years of follow up (Witherspoon et al, Br J Surg 2004; 91:368–372). Despite the widespread use of synthetic mesh in surgical procedures in humans over the past 50 years, there have been few reports of malignancy formation after implantation with prosthetic materials. These concerns have recently been addressed by Moalli et al and it was concluded that polypropylene, which has been used extensively in humans for over five decades, is not associated with carcinogenesis. (Moalli et al, 2014). As stated in the AUGS/SUFU Frequently asked questions by providers-Mid-urethral slings for stress urinary incontinence “There is no compelling evidence supporting human malignant transformation related to polypropylene despite the millions of individuals implanted with various forms of this material

TVT places a women at a significant risk of long term, chronic complications or the need for reoperation as plaintiffs' experts suggest.

At the present time, expert opinion and clinical practice guidelines from a wide group of subspecialty societies, such as the American College of Obstetricians and Gynecologists, American Urogynecologic Society, Society of Gynecologic Surgeons, American Urological Association, Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction and the International Urogynecology Association advocate the polypropylene mid-urethral sling as the standard of care for the surgical treatment of SUI based on data derived from the TVT and acknowledge that it represents a great advance in the treatment of this condition in women. The TVT sling has revolutionized the treatment of SUI for women throughout the world and it has stood the test of time. Its design is useful, desirable and optimal and in my opinion it is reasonably safe for its untended use, to treat stress urinary incontinence. No other design or mesh has been demonstrated to be more effective, safer, or has been studied as much, as long, or in as many patients and types of patients as the TVT has showing that it is safe and effective. The TVT IFU, Surgeons Monograph and Professional Education are clear, useful and adequate to describe the procedure and potential risks. Risks of SUI surgery are obvious to surgeons and as surgeons, we are expected to be aware of the risks in light of our education, training and experience. Because of its utility and positive benefit / risk profile, the TVT has been adapted as the gold standard for its treatment.



Marc Toglia, M.D.

Date: February 25, 2016